UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation **This Document Related To: All Cases**	**22md3043 (DLC)**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTIONS TO EXCLUDE DR. ERIC HOLLANDER

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INTRODUCTION[1]

Dr. Eric Hollander is "a well-intentioned, thoughtful scientist" and someone Defendants' expert, Dr. Kolevzon, "respect[s]." *See* Ex. 28, Kolevzon Dep. Tr. at 124:6–8, 126:17–18.[2] For good reason. Dr. Hollander has unsurpassed credentials and vast experience in the field of neurodevelopment. He served as part of expert workgroups for three editions of the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM") and has edited more than twenty books, including both editions of the *Textbook of Autism Spectrum Disorders*. Dr. Hollander applied that unmatched experience and expertise to render his opinion in this case: prenatal exposure to APAP causes ASD and ADHD in offspring.

Defendants' primary criticism of Dr. Hollander's methodology is that he applied a transdiagnostic approach. In Defendants' telling, that means Dr. Hollander considered *too much* evidence, evaluating "symptom domains [that]. . . cut across ASD and ADHD and map onto their underlying brain circuitry and neurogenic factors." Ex. 23, Hollander Dep Tr. at 344:3–8. For instance, if a study evaluated APAP's effect on hyperactivity or attention deficit (the two symptoms that constitute ADHD)—even without a confirmed ADHD diagnosis—Dr. Hollander reviewed and analyzed that paper. Dr. Hollander pleads guilty as charged. Far from being a methodological flaw, his approach is the standard. The most recent editions of the DSM (the DSM-5) and the International Statistical Classification of Diseases and Related Health Problems (the ICD-11) support his position. So does Defendants' expert, Dr. Faraone, who has applied the

[1] Defendants largely assert the same arguments across Plaintiffs' experts in three omnibus briefs, failing to assert proper Rule 702 challenges against each specific expert's methodology. Plaintiffs incorporate by reference arguments made in response to their Oppositions to the Motions to Exclude Drs. Pearson, Baccarelli, Cabrera, and Louie.

[2] Courts agree with Dr. Kolevzon. *See In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1354 (N.D. Fla. 2018) (finding Dr. Hollander "amply qualified" to offer expert testimony); *see also In re Mirapex Prods. Liab. Litig.*, No. 06-CV-1215, 2008 WL 7505586, at *1 (D. Minn. Apr. 2, 2008) (denying motion to exclude Dr. Hollander's expert testimony).

transdiagnostic approach in over *four dozen* peer-reviewed studies. As Dr. Faraone agrees, it is the *international scientific consensus* that the "shared genetic and environmental risks" between ADHD and other neurodevelopmental disorders, including ASD, "suggest that these disorders also share a pathophysiology in the biological pathways that dysregulate neurodevelopment and create brain variations leading to disorder onset." Ex. 93, Faraone (2021) at 795. For that reason, [redacted] FDA reviewed the broader category of evidence that Defendants now say it was a methodological flaw to even glimpse. Dr. Hollander cannot be excluded for being thorough.

Defendants next take aim at Dr. Hollander's analysis of biological plausibility, doubling down on their erroneous claim that "plausible" means "established." That made-for-litigation alteration of this Bradford Hill factor finds no support anywhere, including from Defendants' own experts. Pearson Opp'n at 10–17. Dr. Hollander's Bradford Hill analysis is a reliable application of that well-accepted methodology. Baccarelli Opp'n at 49–57. That Defendants disagree with Dr. Hollander's conclusions is no basis to exclude them.

Finally, Defendants think Rule 702 asks the Court to administer a memory test, excluding Dr. Hollander for not recalling every detail of his report or the vast literature that supports its conclusions. "An expert is not required to have memorized the complete contents of [his] expert report," and such lapses "are traditionally challenged on cross-examination." *Bd. of Trustees of AFTRA Ret. Fund v. JPMorgan Chase Bank, N.A.*, No. 09 CIV 3020 SAS, 2011 WL 6288415, at *11 (S.D.N.Y. Dec. 15, 2011). Plaintiffs will spend their cross-examination time on more substantive issues, but Defendants are welcome to waste their cross of Dr. Hollander on whether he recalls from memory what every study says. Ex. 23, Hollander Dep. Tr. at 246:9–10 (asking, without allowing Dr. Hollander to review the study, "[D]o you know what Masarwa 2020 says?") A jury will inform them if that time was well spent.

BACKGROUND

I. Dr. Hollander Is a Highly Qualified Psychiatrist.

Dr. Hollander specializes in "psychiatric medicine, neurodevelopmental disorders, and neuropsychopharmacology," Ex. 4, Hollander Rep. at 5 and "ha[s] expertise in all of the neurodevelopmental disorders." Ex. 23, Hollander Dep. Tr. at 27:11–13. He is a Professor of Psychiatry and Behavioral Sciences and the Director of the Autism and Obsessive-Compulsive Spectrum Program at the Psychiatry Research Institute of Montefiore-Einstein at Albert Einstein College of Medicine and Montefiore Medicine in New York. Ex. 4, Hollander Rep. at 5. He is also a fellow of the American College of Neuropsychopharmacology ("ACNP") and a Distinguished Lifetime Fellow of the American Psychiatric Association ("APA"). *Id.*[3] Prior to Dr. Hollander's current appointments, he was a Professor and Chair of Psychiatry at Mount Sinai School of Medicine and an attending psychiatrist at Mount Sinai Hospital, where he supervised Dr. Kolevzon. *Id.* at 6. Before that, he was a member of the faculty at Columbia University College of Physicians and Surgeons and the New York State Psychiatric Institute. *Id.*

Dr. Hollander is a prolific scholar. He has edited 20 books, including both editions of the *Textbook of Autism Spectrum Disorders*, three editions of the *Textbook of Anxiety, Trauma, and OCD Related Disorders*, and the *Clinical Manual of Impulse Control Disorders*. *Id.* Dr. Hollander co-edited the first edition of the *Textbook of Autism Spectrum Disorder* with Dr. Kolevzon, Ex. 28, Kolevzon Dep. Tr. at 52:5–8, and, in the second edition, Dr. Kolevzon co-authored a chapter

[3] A fellow of the ACNP must "have made substantial contributions to the College and to the field of neuropsychopharmacology." *Applications + Nominations*, Am. Coll. Neuropsychopharmacology, https://acnp.org/membership/applications-nominations/ (last visited Sept. 24, 2023). The APA awards the status of Distinguished Fellow to "outstanding psychiatrists who have made significant contributions to the psychiatric profession in at least five of the following areas: administration, teaching, scientific and scholarly publications, volunteering in mental health and medical activities of social significance, community involvement, as well as for clinical excellence." *Become A Distinguished Fellow of the APA*, Am. Psychiatric Ass'n, https://www.psychiatry.org/membership/honorary-fellowship (last visited Sept. 24, 2023).

noting that APAP "has recently been demonstrated to be associated with ASD and ADHD," Ex. 98, Kolevzon Dep. Ex. 494, at 191. Dr. Hollander has served as the principal investigator on federally funded research, including on projects relating to Prader-Willi Syndrome (a neurodevelopmental disorder and syndromic form of ASD), body dysmorphic disorder, autism, and borderline personality disorder. Ex. 4, Hollander Rep. at 8. He is "an expert in ADHD and in neurodevelopmental disorders." Ex. 23, Hollander Dep. Tr. at 155:14–20.

Dr. Hollander also has extensive clinical experience treating a wide variety of neurodevelopmental disorders. Ex. 4, Hollander Rep. at 9; *see* Ex. 23, Hollander Dep. Tr. at 27:11–13. Dr. Hollander has treated people with ASD, ADHD, OCD, Prader-Willi Syndrome, depression, body dysmorphic disorder, anxiety disorders, depersonalization disorder, cataplexy, trichotillomania, sleep disorders, and pain disorders. Ex. 4, Hollander Rep. at 9; Ex. 23, Hollander Dep. Tr. at 18:21–24. In the clinical setting, he advises patients "who were pregnant or women who were considering becoming pregnant" about "risks and benefits of taking any medication during pregnancy." Ex. 23, Hollander Dep. Tr. at 230:14–231:16. Dr. Hollander advises pregnant patients that "the risks" of using APAP for pain "may outweigh the benefits," such that the patients "should take the absolute smallest number of doses for the shortest period of time and to consider other alternatives." *Id.* at 231:17–232:7; *see also id.* at 234:13–16 ("I would encourage [my patients] not to take acetaminophen unless absolutely necessary. For example, for high fever."); *id.* at 240:17–21 ("I have recommended to my patients who were pregnant or considering getting pregnant that . . . it was not safe to use acetaminophen and that they would be at increased risk.").[4]

[4] Dr. Hollander's advice to pregnant patients mirrors Plaintiffs' proposed label *and* what Defendants' own maternal-fetal medicine expert, Dr. Mary D'Alton, advises. *See* Ex. 27, D'Alton Dep. Tr. at 251:1–10 (testifying that during pregnancy "the lowest dose of a medication for the shortest period of time should be used"); *id.* at 286:5–12 (same).

Dr. Hollander "routinely make[s] assessments of potential causal associations" and attempts to "understand[] and examin[e] the underlying causes and mechanisms of those disorders." Ex. 4, Hollander Rep. at 9. As a result of his clinical and research experience, Dr. Hollander has "identif[ied] commonalities among many neurodevelopmental disorders." *Id.* And, in ASD and ADHD patients in particular, Dr. Hollander has found the two disorders "are likely to overlap symptomatically or be comorbid with each other or with other neurodevelopmental disorders." *Id.* at 10.

II. Dr. Hollander's Methodology and Opinions.

Dr. Hollander conducted a literature search of "searchable databases such as PubMed" using terms "relating to exposure and outcome." Ex. 23, Hollander Dep. Tr. at 191:8–24. Applying the "transdiagnostic approach," which recognizes "the interconnectedness of neurodevelopmental disorders, including ADHD and ASD," Dr. Hollander determined "it is appropriate to review the body of evidence that measures symptoms of neurodevelopmental disorders and not to limit the analysis to studies that focus on ASD and ADHD as specified outcomes when evaluating the potential causal association between prenatal APAP exposure and ASD and ADHD in offspring," Ex. 4, Hollander Rep. at 4. That body of evidence includes "well-studied and validated questionnaires and assessments . . . used in the epidemiological literature" because they "are highly similar to diagnoses by healthcare professionals, and may be more sensitive and accurate reflections of the symptom domains within a neurodevelopmental disorder than the DSM diagnostic criteria." Ex. 9, Hollander Rebuttal Rep. at 28. After collating and reviewing the relevant evidence, Dr. Hollander performed a Bradford Hill analysis, concluding that there is a causal relationship between prenatal use of APAP and ASD and ADHD in offspring. *Id.* at 14–21; Ex. 4, Hollander Rep. at 75–86.

A. The Transdiagnostic Approach to Neurodevelopmental Disorders.

Defendants' principal objection is that Dr. Hollander should have myopically limited his literature review to studies that evaluated confirmed ASD and ADHD diagnoses as endpoints. Peer-reviewed publications, widely used textbooks, FDA, and JJCI itself all reject that critique. The transdiagnostic approach is appropriate (in fact, necessary) because ASD and ADHD are not two distinct diseases, each with a separate and uniform presentation. They are each heterogeneous diseases with overlapping presentation and a shared neurodevelopmental origin.

ASD and ADHD are both diagnosed based solely on behavioral symptoms. DSM-5 at 50–51, 59–61. ASD symptoms are deficits in social communication and interaction, and restricted or repetitive patterns of behavior, interests, or activities. *Id.* at 50–51. ADHD symptoms are attention deficits and hyperactivity. *Id.* at 59–61. Each of these symptoms appears along a spectrum from non-existent to mild to severe. *See* Ex. 31, Faraone Dep. Tr. 155:23–156:8 ("So if you measure [ADHD] symptoms in the population, you get roughly a normal distribution of symptoms . . . . ***But in that sense, it's a spectrum in a population***." (emphasis added)); *see also* Ex. 95, Khoury (2022) at 352 ("The spectrum view of ADHD may decrease the stigma of the disorder, which in itself would significantly reduce ADHD disparities. This aligns with newer transdiagnostic perspectives on psychiatric disorders."). The result is a heterogeneous multiplicity of symptom patterns. The DSM-5 categorizes the symptom patterns that emerge as either ASD, ADHD, or comorbid ADHD and ASD. DSM-5 at 50–51, 59–61. Dr. Faraone reports that about 60% of children with ASD meet diagnostic criteria for ADHD, and over 65% of children with ADHD have clinically significant difficulties in both language and social interaction based on the Autism Criteria Checklist. *See* Ex. 94, Antschel (2013) at 1118–20.

It is also accepted that ASD and ADHD have the same neurodevelopmental causes. Dr. Faraone published a peer-reviewed study demonstrating that ASD and ADHD have common

"biological," "neuropsychological," and "behavioral" features. *Id.* The study reported "similar neurobiological pathways for ADHD and ASD," including that "oxidative stress has been observed in both ADHD and autism," and that "many environmental risk factors" are shared between ASD and ADHD. *Id.* at 1118. In addition, Dr. Faraone's 2023 genetics study found that 84% of the gene variants associated with ADHD were also associated with ASD. *See* Ex. 91, Demontis (2023) at 204.

As a result, Dr. Faraone agrees that these symptom patterns for both diseases arise from the same set of neurodevelopmental disruptions. As the World Federation of ADHD's International Consensus Statement led by Dr. Farone declares, it is the *scientific consensus* that that the "shared genetic and environmental risks" between ADHD and other neurodevelopmental disorders including ASD "suggest that these disorders also share a pathophysiology in the biological pathways that dysregulate neurodevelopment and create brain variations leading to disorder onset." Ex. 93, Faraone (2021) at 795.

The DSM-5 published in 2013 recognized that these heterogeneous symptom patterns were not unrelated. It replaced "five separate pervasive developmental disorders" identified in earlier editions of the DSM with the "spectrum" disorder now known as ASD. Ex. 4, Hollander Rep. at 13. And it combined ASD, ADHD, and other neurodevelopment disorders in a new chapter titled "Neurodevelopmental Disorders." *Id.*; *see also* Ex. 31, Faraone Dep. Tr. at 60:4–19 (explaining that the DSM defines ASD, ADHD, and other neurodevelopmental disorders "as neurodevelopment because it's believed that their pathogenesis occurs during the development of the brain"). The DSM-5 also "allows for a dual diagnosis of ASD and ADHD, recognizing the *significant overlap* of these disorders and that they frequently co-occur." Ex. 4, Hollander Rep. at 61 (emphasis added); *see also* Ex. 92, Doernberg & Hollander (2016) at 298 (describing changes

to the DSM, including allowing "a comorbid diagnosis" of ASD and ADHD). The shift away from rigid diagnostic categories is a validation of the transdiagnostic approach Dr. Hollander deployed.

The federal government also endorses Dr. Hollander's methodology. The National Institute of Mental Health's ("NIMH") Research Domain Criteria ("RDoC") Initiative follows a similar path of reducing emphasis on diagnostic categories. It "considers mental health and psychopathology in the context of major domains of basic human neurobehavioral functioning, rather than within established diagnostic categories." Ex. 113, About RDoC; Ex. 4, Hollander Rep. at 11; *see also* Ex. 92, Doernberg & Hollander (2016) at 298 (describing RDoC as a "shift . . . away from defining disorder based on descriptive phenomenology and focusing instead on neural circuitry"). The framework was developed by "over 200 leading scientists" and "launched in 2009." Ex. 113, About RDoC. It includes "six major functional domains" that "are represented by three to six psychological/biological dimensions, or constructs, which are studied along the full range of functioning from normal to abnormal." *Id.* (emphasis omitted). By focusing on "functional domains" rather than diagnostic categories, the RDoC framework addresses "problems with heterogeneity," "comorbidity," and "somewhat arbitrary" clinical diagnosis criteria to help researchers identify important information, including "how risk factors operate." *Id.*

NIMH has funded transdiagnostic research projects under its RDoC Initiative since at least 2012, awarding over $53 million in grants. Ex. 117, RDoC Projects. That amount includes over $600,000 awarded to a project "to study new ways of classifying mental disorders in children based on observable behavior and genetics" led by Dr. Faraone.[5] Dr. Faraone's NIMH grant for a transdiagnostic project has resulted in 52 peer-reviewed publications utilizing the transdiagnostic

[5] *Longitudinal Family/Molecular Genetic Study to Validate Research Domain Criteria*, Nat'l Library of Med., https://clinicaltrials.gov/study/NCT02415647 (last visited Oct. 9, 2023).

approach, several of which Dr. Hollander reviewed in reaching his opinions. *See, e.g.*, Ex. 97, Faraone & Larsson (2019) at 566 (noting "genetic overlap between ADHD and ASD"); Ex. 90, Biederman (2021) at 11 (using the Child Behavior Checklist to identify "the type and severity of potential comorbid psychopathological conditions that may be affecting referred youths with suspected ADHD"); Ex. 93, Faraone (2021) at 806 (noting that some causes of ADHD "may be shared with ADHD's somatic comorbidities" including "oxidative stress"). Dr. Faraone's transdiagnostic work is consistent with other studies that Dr. Hollander considered in forming his opinions. *See, e.g.*, Ex. 104, Scheerer (2022) at 11 (reporting results that "demonstrate that sensory processing abilities in neurodevelopmental conditions are transdiagnostic in nature"); Ex. 100, Kushki (2019) at 7 ("[O]ur results suggest that homogeneity in the variables examined in our analyses does not align well with existing diagnostic categories."); Ex. 103, Morris-Rosendahl & Crocq (2020) at 69 ("[C]hildhood neurodevelopmental disorders ([intellectual disability], ASD, ADHD) . . . could be better conceptualized as lying on an etiological and neurodevelopmental continuum, rather than being defined as discrete entities.").

Moreover, among the 52 peer-reviewed scientific articles published in conjunction with Dr. Faraone's RDoC project, several speak directly to the merits of considering ASD and ADHD research together with findings about related neurodevelopmental disorders. For example, in Mattheisen, Dr. Faraone identified shared genetic etiology between ADHD and ASD. *See generally* Ex. 102, Mattheisen (2022). In Barnett, Dr. Faraone found that polygenic risk scores for ADHD and four other neurodevelopmental disorders could help identify the presence of mood disorders. The authors concluded: "These findings extend evidence for transdiagnostic genetic components of psychiatric illness and demonstrate that [polygenic risk scores] calculated using traditional diagnostic boundaries can be useful within a transdiagnostic framework." Ex. 89,

Barnett (2022). And in a 2021 study, Dr. Farone explained and endorsed the "spectrum view of ADHD," which "aligns with newer transdiagnostic perspectives on psychiatric disorders." Ex. 95, Khoury (2021) at 352.

Consistent with the transdiagnostic approach, in considering diverse outcome measurements, it is standard practice to rely on studies that use data from validated scales and other assessments. *See* Ex. 9, Hollander Rebuttal Rep. at 23–28. In the clinical setting, ASD and ADHD are diagnosed solely based on behavioral symptoms that appear along a spectrum of severity. *See* Ex. 4, Hollander Rep. at 62–63 & App'x 1–2. And to make the diagnosis, each symptom domain (social and communication deficits, repetitive patterns, hyperactivity, and attention deficits) is separately graded by using validated scales and assessment instruments. *See* Ex. 9, Hollander Rebuttal Rep. at 23–28; *see also* Ex. 4, Hollander Rep. at App'x 3. Therefore, the results of such instruments are not just highly correlated with ASD and ADHD diagnosis, they are often the *very* tools used by clinicians to arrive at a diagnosis. *See, e.g.*, Ex. 90, Biederman (2021) at 3–4 (Dr. Faraone collecting diagnostic and screening uses of the Child Behavior Checklist). For that reason, as Dr. Hollander notes, such instruments are a "frequently used and well-validated method of research." Ex. 9, Hollander Rebuttal Rep. at 24. The "well validated methods" act as proxies for ASD or ADHD diagnoses or "identify symptomology consistent with neurological damage, including ADHD and ASD." *Id.* Importantly, using "instruments to characterize individual components of the ASD phenotype" may avoid "bypassing crucial differences within the group." Ex. 99, Jones & Lord (2013) at 113. Table 1 below contains multiple peer-reviewed publications showing that outside-of-litigation scientists reject Defendants' criticism of the transdiagnostic approach.

Table 1. Validation of Outcome Measures Used in APAP Studies

Assessment	APAP Studies Using Assessment	Studies Validating Assessment[6]
Strengths & Difficulties Questionnaire ("SDQ")	• Tovo-Rodrigues (2018) • Stergiakouli (2016) • Thompson (2014) • Liew (2014) (also used hospital diagnosis, ADHD medication) • Inoue (2021) • Rifas-Shiman (2020) (also used BRIEF assessment) • Golding (2019)	• **Algorta (2016)** (finding that "the SDQ for Parents is a statistically valid tool for discriminating cases with ADHD from those without ADHD"). • **Russell (2013)** ("All SDQ subscales were strongly associated with both ASD and ADHD."). • **Riglin (2021)** (reporting "excellent validity of the self-rated SDQ for measuring ADHD in young adulthood"). • **Overgaard (2019)** (reporting "screening accuracy for the [hyperactivity-inattention subscale] was good" for predicting ADHD in the participants in the DNBC).
Child Behavior Checklist ("CBCL")	• Sznajder (2022) • Alemany (2021) (also used DSM questionnaire) • Tronnes (2020) (also used ASQ, EAS, parent reports) • Parker (2020) (also used teacher report) • Tovo-Rodrigues (2020) (also used BDI) • Brandlistuen (2013) (also used ASQ, EAS) • Vlenterie (2016) (also used ASQ)	• **Levy (2019)** (reporting that CBCL "may be an effective means of identifying children with ASD features"). • **Rescorla (2020)** ("[O]ur strong measurement findings support the international psychometric robustness of the CBCL's 1½ – 5's DSM-ASD scale."). • **Mazefsky (2011)** ("The CBCL scorers could be used to differentiate the ASD groups from the typically-developing control group with a high degree of sensitivity (.97) and specificity (.96)[.]"). • **Arias (2022)** (replicating results that support using CBCL "as a screener for ASD"). • **Biederman (2021)** (finding "the CBCL can provide clinicians . . . with useful details about the type and severity of potential comorbid psychopathological conditions . . . affecting youths with suspected ADHD"). • **Oerbeck (2020)** (finding the CBCL is "useful for predicting ADHD"). • **Spencer (2018)** (reporting, with co-author Dr. Faraone, that the CBCL "accurately identified ADHD" and "distinguished complex from simple ADHD").
Ages & Stages Questionnaire	• Tronnes (2020) (also used CBCL, EAS,	• **Richter & Janson (2007)** (finding the ASQ "to be an effective diagnostic tool of

[6] *See* Hollander Rep., App'x 3; Hollander Rebuttal Rep. at 23–28.

("ASQ")	parent reports) • Brandlistuen (2013) (also used CBCL, EAS) • Vlenterie (2016) (also used CBCL)	developmental delay and/or disturbances")
Childhood Autism Screening Test ("CAST")	• Avella Garcia (2016)	• **Williams (2005)** ("The CAST is useful as a screening test for autism spectrum conditions in epidemiological research."). • **Williams (2006)** ("The CAST has shown good test-retest reliability.").
Developmental & Well-Being Assessment ("DAWBA")	• Ruisch (2018) (also used nurse evaluation, parent questionnaire)	• **Foreman (2009)** (finding "the predictive value of a positive or negative DAWBA diagnosis was greater than .8, with negligible bias"). • **Murphy (2018)** (reporting "the DAWBA predicted consensus diagnosis with good sensitivity and specificity" such that it "could replace" other diagnostic tools).

Further, use of validated proxy measures is consistent with NIMH's RDoC framework that encourages researchers "to measure and integrate many classes of variables (units of analysis, e.g., behavioral, physiological, *and self-report data*) in order to seek a comprehensive understanding of the construct(s) under study." Ex. 113, About RDoC (emphasis added). Self-reported data includes information gathered from "interview-based scales, self-report questionnaires, or other instruments that may encompass normal-range and/or abnormal aspects of the dimension of interest." Ex. 119, RDoC Unit of Analysis; *see also* Ex. 118, RDoC Unit of Analysis: Self-Reports (providing a non-exclusive list of scales and questionnaires that may be used to capture self-report data); Ex. 4, Hollander Rep. at App'x 3 (describing common assessments for ASD and ADHD); Ex. 9, Hollander Rebuttal Rep. at 23–28 (describing ASD and ADHD assessments and validation studies). These types of outcome measures allow researchers to identify neurodevelopmental dysfunction without being tied to the "somewhat arbitrary" clinical diagnostic categories. Ex. 113, About RDoC; *see also* Ex. 99, Jones & Lord (2013) at 114.

Dr. Hollander's approach should be familiar to Defendants. Both FDA [redacted] *See*, *e.g.*, FDA Review (July 15, 2022), Dkt. 427-7; [redacted] FDA took a similar approach. *See* FDA Review (May 15, 2014), Dkt. 427-4 (reviewing Liew (2014), which used data from assessments); FDA Review (Mar. 18, 2015), Dkt. 427-5 (reviewing Thompson (2014), which used data from assessments); FDA Review (Oct. 14, 2016), Dkt. 427-6 (reviewing 4 studies that all used data from assessments); FDA Review (July 15, 2022), Dkt. 427-7 (showing that of the 31 studies reviewed, only 12 used clinical diagnoses and 19 used other assessments).

Outside of litigation, Dr. Hollander's approach is de rigueur. And everyday scientific practices are the preferred yardsticks to measure the propriety of a methodology. *See Daniels-Feasel v. Forest Pharms., Inc.*, No. 17 CV 4188-LTS-JLC, 2021 WL 4037820, at *4 (S.D.N.Y. Sept. 3, 2021) ("The district court must also ensure that experts are employing in the courtroom

the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.") (citation and quotation marks omitted).

B. Dr. Hollander's Bradford Hill Analysis.

Prior to issuing his Rule 26 report, Dr. Hollander reviewed the underlying epidemiologic literature for the association between prenatal use of APAP and ASD/ADHD. In response to the analyses undertaken by Defendants' experts, Dr. Stephen Faraone and Dr. Alexander Kolevzon, Dr. Hollander undertook a Bradford Hill analysis in his rebuttal report to "illustrate[] the shortcomings" of their "analyses and opinions." Ex. 9, Hollander Rebuttal Rep. at 2.[7] He relied extensively on the written assessment of the studies in Dr. Baccarelli's report.

Dr. Hollander opined that in utero exposure to APAP can cause the neurodevelopmental disorders of ASD and ADHD. Ex. 23, Hollander Dep. Tr. at 242:5–10; *see also* Ex. 9, Hollander Rebuttal Rep. at 14–21. Dr. Hollander assigned the most weight to the Bradford Hill factors of dose response, biological plausibility, coherence, consistency, and strength of association. Ex. 9, Hollander Rebuttal Rep. at 3. Dr. Hollander identified plausible biological mechanisms of action by which prenatal use of APAP can cause ASD and ADHD, including oxidative stress caused by excess NAPQI formation/GSH reduction, Ex. 4, Hollander Rep. at 76–78; disruption of the prostaglandin system, *id.* at 79; endocannabinoid dysfunction, *id.* at 79–81; endocrine disruption, *id.* at 82; altered brain development neurotropic factor, *id.* at 82–83; and epigenetic defects, *id.* at 83–86.[8] Far from being "scientific guesswork," Defs. Mechanism Br. at 2, Dkt. 1165, these biological mechanisms have *all* been identified in published, peer-reviewed articles.

[7] Dr. Hollander held the opinion that APAP can cause ASD and ADHD prior to his initial report. Ex. 23, Hollander Dep. Tr. at 29:6–21.

[8] Defendants attempt to argue that Dr. Hollander limited the plausible biological mechanisms to oxidative stress, endocannabinoid disruption, and epigenetic changes during his deposition. *See* Defs. Mechanism Br. at 9. But Dr. Hollander merely identified those as "important" biological mechanisms and in no way withdrew his opinion as to the prostaglandin system and altered brain development neurotropic factors as plausible biological mechanisms. *See* Ex.

LEGAL STANDARD

Plaintiffs refer the Court to the Rule 702 legal standard set forth in Plaintiffs' Baccarelli Opposition at 33–34.

ARGUMENT

Defendants do not and cannot dispute that Dr. Hollander is qualified or that his testimony would be helpful to the trier of fact. Instead, Defendants argue that the Court should exclude Dr. Hollander's opinion because he relied on too much scientific evidence, misapplied the Bradford Hill factors, and lacked total recall at his deposition. None of Defendants' arguments is faithful to Rule 702 and binding precedent construing it.

I. Dr. Hollander's Opinions Regarding the Overlap of ASD and ADHD and Use of Questionnaires-Based Studies Are Admissible.

Defendants say the transdiagnostic approach "has no scientific support." Defs. ASD Br. at 3, Dkt. 1160. That is false. Dr. Hollander's report and materials considered list are replete with examples of peer-reviewed scientific studies that apply the transdiagnostic approach. It is generally accepted in the scientific community. Defendants claim that ASD and ADHD must be considered separately because they have "distinct sets of diagnostic criteria." Defs. ASD Br. at 45; *see generally* Defs. ADHD Br. at 17–18, Dkt. 1162. But Defendants' conclusion does not follow from their premise. That a disorder has a "distinct set of diagnostic criteria" does not mean that it does not share important, relevant *etiologies* with other disorders or symptomologies. That well-accepted fact is precisely why the transdiagnostic method is so frequently used in Dr. Hollander's field. Any dispute on this score is a "debate [] best heard by a jury." *United States v. Jones*, 965 F.3d 149, 160 (2d Cir. 2020); *cf. Ake v. Oklahoma*, 470 U.S. 68, 81 (1985)

23, Hollander Dep. Tr. at 381:25–382:6.

("[P]sychiatrists disagree widely and frequently on what constitutes mental illness, [and] on the appropriate diagnosis to be attached to given behavior and symptoms . . . .").

Basic logic supports the widespread use of the transdiagnostic approach. Both ASD and ADHD are dimensional disorders that are diagnosed based on the presence of certain behavioral symptoms. Ex. 4, Hollander Rep. at 13, 38. It follows *per force* that studies measuring for *those* symptoms are *relevant* to evaluating the disorders themselves. And studies showing that an agent can cause those symptoms are relevant to whether the agent can cause the disorders. That is the consensus of the scientific community. *See* Table 1, *supra* (identifying studies that validate the use of non-diagnostic assessment tools); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593–94 (1993) (outlining indices of reliability where the methodology "has been subjected to peer review and publication" or has "[w]idespread acceptance" in the "scientific community"). And it is well within Dr. Hollander's expertise as a clinician and scientist to follow that consensus. *See In re Foxamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 181 (S.D.N.Y. 2009) (finding expert's conclusion to be "highly indicative of [] reliability" where it "appears to have attained some measure of consensus among practitioners."). To be sure, *all else equal*, a study reporting confirmed ASD or ADHD diagnoses would be more probative than a study providing self-reported symptoms of those conditions. But that goes to the weight to give the former, not the *relevance* of even considering the latter.

Importantly, the inference Dr. Hollander draws from the peer-reviewed "proxy studies" is consistent with the conclusions drawn by the study authors themselves. For example, in Avella-Garcia (2016), which used the CAST assessment tool to measure symptoms of neurodevelopmental disorders, *see* Table 1, *supra*, the authors noted, "[o]ur findings agree with reports of an association between prenatal exposure to acetaminophen and ADHD behaviors,

diagnosis, or medication use in childhood and with an ecological study that reported an association with [ASD] prevalence." Ex. 39, Avella-Garcia (2016) at 1993. One of the study's strengths was "the use of multiple endpoints [to] provide[] a comprehensive evaluation of different areas of child neurodevelopment." *Id.* Similarly, Liew's 2014 study identified the use of the SDQ assessment as a "major strength" that allowed the authors "to assess the outcome addressing different levels of ADHD." Ex. 44, Liew (2014) at 318. And, notably, the *vast majority* of the "proxy" study authors place no limits on the propriety of drawing an inference from assessment-based outcome measures to clinical diagnoses of ASD and ADHD.[9]

Dr. Hollander also supports use of the transdiagnostic approach with evidence of shared neurobiology among ASD, ADHD, and other neurodevelopmental disorders. The Vandewouw study "suggests that homogeneity in neurobiology transcends diagnostic boundaries, promoting a shift in the research community away from classic case-control designs that rely on diagnostic categories, which have increasingly been shown not to reflect distinct biological and phenotypic constructs." Ex. 107, Vandewouw (2023) at 12; *see also* Ex. 4, Hollander Rep. at 11–12 (discussing Vandewouw). Defendants complain that Vandewouw did not "offer any claims about what environmental factors may be associated with either condition, much less cause each one." Defs. ASD Br. at 46. But nothing in Dr. Hollander's report suggests that Vandewouw made such claims. To the contrary, Dr. Hollander's report makes clear that he relies on Vandewouw to support his opinion that ASD, ADHD, and other neurodevelopment disorders *overlap* in many ways. No more and no less. Ex. 4, Hollander Rep. at 11–12.[10]

[9] In fact, some authors affirmatively stated such an inference can be drawn. *See, e.g.*, Ex. 105, Thompson (2014) at 3. (noting that rating scale could be "used to identify a probable diagnosis of ADHD"); Ex. 108, Vlenterie (2016) at 2006 (noting that "[w]ell-known and internationally recognized measurements . . . correlated well with the diagnostics").

[10] Defendants latch on to a single "editorial" that Dr. Hollander cites, as if that is the only support he offers for his method. Defs. ASD Br. at 46. But, as noted *supra*, his materials considered list is chock-full of peer-reviewed

In addition to the published literature, Dr. Hollander relied on his own vast research and clinical experience to show that "symptom domains . . . cut across ASD and ADHD and map onto their underlying brain circuitry and neurogenic factors." Ex. 23, Hollander Dep Tr. at 344:3–8. Expert testimony may be based on "experience alone—or experience in conjunction with other knowledge, skill, training or education." Fed. R. Evid. 702 Advisory Comm.'s Note. Indeed, "[i]n certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony." *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 413 (S.D.N.Y. 2016) (quoting Fed. R. Evid. 702 Advisory Committee's Note); *see SR Int'l Bus. Ins. Co. v. World Trade Ctr. Props., LLC*, 467 F.3d 107, 132 (2d Cir. 2006) (allowing an expert to testify on custom and practice based on experience where he explained how his experiences informed his testimony). Dr. Hollander's "extensive experience diagnosing and treating neurodevelopmental disorders" informs his approach to and interpretation of the scientific evidence relevant to this case. Ex. 4, Hollander Rep. at 9. "Clinicians must take a transdiagnostic approach in their assessments [of ASD and ADHD]"; otherwise "the similarities in behavioral profiles between these disorders could lead to challenges in both the diagnosis and intervention efforts." *Id.* at 62–63.

Defendants' out-of-circuit cases do not support their position. In *Rider v. Sandoz Pharmaceuticals*, the court held that the district court properly rejected evidence that a cause of one type of stroke necessarily causes another type of stroke that "involve[s] a wholly different biological mechanism." 295 F.3d 1194, 1202 (11th Cir. 2002). This assertion was "supported by little more than the fact that both conditions are commonly called strokes." *Id.* But Dr. Hollander does not rely on the fact that ASD and ADHD are "commonly called" neurodevelopmental

literature that deploys the transdiagnostic approach in this very area. *Cf. Kilpatrick v. Breg, Inc.*, No. 08-10052-CV, 2009 WL 2058384, at *7 (S.D. Fla. June 25, 2009) (excluding expert where expert relied on editorial he authored as only one of four articles used to support his general causation opinion).

disorders. He bases his broader literature review on the undisputed fact that they are disorders that *share* gene by environment origins and symptomologies. *See, e.g.*, Ex. 97, Faraone & Larsson (2019) at 566 (noting "genetic overlap between ADHD and ASDs"); Ex. 104, Scheerer (2022) at 11 (reporting results that "demonstrate that sensory processing abilities in neurodevelopmental conditions are transdiagnostic in nature"); *see generally* Ex. 107, Vandewouw (2023).

In *Burst v. Shell Oil Co.*, the court excluded evidence based on an expert's reliance on scientific studies examining the risk of leukemia generally, rather than "the specific type of leukemia . . . relevant to the general causation question at issue." No. 14-109, 2015 WL 3755953, at *13 (E.D. La. June 16, 2015). But in that case, the expert offered no explanation for *why* it might be appropriate to consider other types of leukemia. *See id.* at *4 (indicating the expert "provides no other explanation of his methodology"). The opposite is true here. Dr. Hollander explains in detail that it is generally accepted to consider evidence relating to ASD, ADHD, and related neurodevelopmental disorders because of the ample scientific evidence that the disorders share certain "neural, genetic, physiological, structural, and psychological traits." Ex. 4, Hollander Rep. at 11. Defendants can disagree as a matter of disputed fact. They cannot ask this Court to embrace their litigation position as a matter of law. *In re Ephedra Prods. Liab. Litig.*, No. 04 MD 1598 (JSR), 2005 WL 8178810, at *6 (S.D.N.Y. Sept. 20, 2005) ("*Daubert* was designed to exclude 'junk science.' It was never intended to keep from the jury the kind of evidence scientists regularly rely on in forming opinions of causality simply because such evidence is not definitive.").

In a related vein, Defendants ignore Dr. Hollander's extensive discussion of how assessment questionnaires—as opposed to clinical diagnoses alone—are generally accepted in the field and supported by peer-reviewed studies. Defs. ADHD Br. at 31–37; Defs. ASD. Br. at 38–43; *see also* Ex. 9, Hollander Rebuttal Rep. at 23–28. That screening assessments may be

overinclusive—*i.e.*, including people who may not have ASD or ADHD in the adverse outcome group—does not invalidate the observed associations; it certainly does render them *irrelevant*. To bias the results away from the null, a screening assessment would have to result in false positives when a mother took APAP, but *not* create false positives when a mother did *not* take APAP. Defendants have not identified any study upon which Dr. Hollander bases his opinion that suffers from such hard-to-fathom bias.[11] As Dr. Hollander notes, overinclusive screening tools "would not be expected to bias the results away from the null." Ex. 9, Hollander Rebuttal Rep. at 12; Ex. 23, Hollander Dep. Tr. at 248:3–9; *see also* Ex. 35, Ref. Manual at 589 (3d ed. 2011) ("Generally, nondifferential misclassification bias leads to a shift in the odds ratio toward one, or, in other words, *toward a finding of no effect*." (emphasis added)); *see* Ex. 88, Weinstein Dep. Tr. at 206:12–24 (explaining that non-differential misclassification usually biases towards the null).

Finally, it is worth noting that the questionnaire-based studies form only a part of the bigger evidentiary picture. The literature with ASD and ADHD endpoints standing on its own—the precise parameters Defendants demand—would still support a causal finding. The additional studies add even more weight to that conclusion. Baccarelli Opp'n at 41–44.

II. Dr. Hollander's Bradford Hill Analysis Is Reliable.

Dr. Hollander reliably applied the Bradford Hill factors to conclude that "prenatal exposure to APAP can cause ASD and ADHD in offspring." Ex. 9, Hollander Rebuttal Rep. at 21. Defendants criticize Dr. Hollander for applying a single Bradford Hill analysis to ASD and ADHD, but as already discussed, the transdiagnostic approach and related literature support his methodology. *See supra* at 15–20. Defendants also lodge the same "results-oriented" and "cherry-

[11] Not to mention that several studies, including Ji (2020) and Baker 2020), mitigate misclassification bias altogether by using biomarker exposure data and physician-diagnosed outcomes. Those studies report positive associations between prenatal APAP exposure and ASD/ADHD that are consistent with other epidemiological studies, suggesting that misclassification bias is minimal even in "proxy" studies.

picking" arguments against Dr. Hollander that they lodge against Plaintiffs' other experts. *See* Defs. ADHD Br. at 2, 19, 20–22, 24, 25, 27, 30–31, 37–38; Defs. ASD Br. at 27–32, 33–38, 41–43, 45. Defendants' criticisms are refuted in Plaintiffs' Baccarelli Opposition. A few additional points are warranted.

Plausible Biological Mechanism: Dr. Hollander outlined plausible biological mechanisms. "The concept of biological plausibility, which numbers among the nine Hill viewpoints, asks whether the hypothesized causal link is credible in light of what is known from science and medicine about the human body and the potentially offending agent." *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 25 (1st Cir. 2011) (criticizing the district court for conflating "the scientific question of biological plausibility with the legal question of probability."). Far from being "wildly speculative," [redacted] Defendants' experts have also outlined these mechanisms. *See* Ex. 98, Kolevzon Dep. Ex. 494 at 191; Ex. 28, Kolevzon Dep. Tr. at 514:23–515:13; *see also* Ex. 96, Joseph (2015) at 920–21 ("[O]ur meta-analysis provide preliminary, suggestive evidence that oxidative stress plays a role in the pathophysiology of ADHD" and that "[o]xidative stress has been implicated in autism."); *see also* Ex. 31, Faraone Dep. Tr. at 166:5–22 ("So this is part of – this is part of the – one area of research, which is the idea that mitochondria may be involved in ADHD or other psychiatric disorders."). And other scientists have agreed that the biological plausibility factor of Bradford Hill is satisfied. *See, e.g.*, Ex. 37, Alemany (2021) at 1000; Ex. 43,

[12] For a full discussion on this point, see Plaintiffs' Pearson Opposition at 10–17.

[redacted]

Bauer (2018) at 135–37. At the very least, those mechanisms are "credible in light of what is known from science and medicine about the human body" and APAP. *Milward*, 639 F.3d at 25.

Coherence: Dr. Hollander found coherence because "the fetal brain is particularly susceptible to environmental insults during development, and environmental factors like pharmaceuticals." Ex. 9, Hollander Rebuttal Rep. at 17; *see also* Ex. 4, Hollander Rep. at 75. Dr. Hollander also noted that ecological evidence supports coherence, citing the corresponding rates of ASD and APAP use in California. *See* Ex. 9, Hollander Rebuttal Rep. at 17 (citing Becker & Schultz (2010)). Defendants dispute Becker & Schultz (2010), but they fail to counter Dr. Hollander's main point—that environmental factors during pregnancy are known to affect a child's neurodevelopment—or in any way point to evidence that would "seriously conflict" with the causal link between prenatal use of APAP and ASD/ADHD. Likely for this reason, the Alemany authors also agreed with Dr. Hollander that the coherence factor was satisfied. Ex. 37, Alemany (2021) at 1000.

Experiment: Dr. Hollander found experiment satisfied based on ecological evidence, Becker & Schultz (2010), as well as the preclinical evidence. Ex. 9, Hollander Rebuttal Rep. at 19–20. It is valid to consider preclinical evidence, which is plentiful, when assessing this factor. *See* Ex. 63, Modern Epidemiology at 71 ("Experimental evidence may refer to clinical trials, to animal experiments, or to experiments on tissues."). Dr. Hollander's analysis of this factor was reliable.

III. Dr. Hollander Is Not Required to Memorize His Report to Testify.

Defendants contend that the Court should exclude Dr. Hollander because he confused facts about certain studies or failed to remember particular items in his report. *See* Defs. ASD Br. at 24–25; Defs. ADHD Br. at 57–58. "This argument lacks merit. Memory lapses are traditionally challenged on cross-examination. An expert is not required to have memorized the complete

contents of [his] expert report." *Bd. of Trustees of AFTRA Ret. Fund v. JPMorgan Chase Bank, N.A.*, No. 09 CIV 3020 SAS, 2011 WL 6288415, at *11 (S.D.N.Y. Dec. 15, 2011).

A failure to memorize all aspects of the sprawling literature in this case, or hundreds of pages of a report, is not a basis to exclude an expert under Rule 702. If it were, Defendants would have serious problems of their own. *See, e.g.*, Ex. 26, Chung Dep. Tr. at 217:10–21 ("Q: Dr. Pearson has done studies on acetaminophen and neurotoxicology, hasn't he? A: I – I'm not aware of his studies. Those – I did not do any studies with him with acetaminophen. Q: You're not aware of his research on acetaminophen? A: I'm not. Q: I think it's in your report, isn't it? A: I don't recall. Maybe you can point it out to me."); Ex. 27, D'Alton Dep. Tr. at 280:3–17 ("Do you recall what the confidence intervals in the Gustavson paper in the sib-pair cohort were? A: I would have to look it up. I can't recall that at this moment. Q: Well, you said you thought they were statistically significant. Remember that a minute ago? A: As far as I remember, they eliminated the risk, but I'd have to look back to confirm that."); Ex. 29, McGill Dep. Tr. at 367:18–368:2 ("Q: I'm not producing a copy, but it's on page 3 of your materials referred list or your reference list, so – A: Yeah, I don't recall what their claimed evidence for oxidative stress is. I would need to review that if you want me to make a meaningful statement about it. Again – Q: We were hoping you would have reviewed it in your report, Dr. McGill.").

Defendants are free to test Dr. Hollander's memorization skills during cross examination. Rule 702 does not require total recall in order to testify.

CONCLUSION

For the foregoing reasons, the Court should deny Defendants' motions to exclude Dr. Hollander's expert testimony.

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Respectfully submitted,

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